

REMARKS

In view of the following remarks, the Office is respectfully requested to allow Claims 11, 13-15, 18, 27, 30-31 and 34, as well as new Claims 42-44, the only claims pending and under examination in this application.

Claims 1-10, 12, 16-17, 19-26, 28-29, 32-33 and 35-41 stand previously cancelled without prejudice against their reintroduction into this or any other timely filed continuation, divisional or continuation-in-part applications.

By this amendment, independent Claims 11, 27 and 31 are amended for clarity to delete the phrase “a P-foot flanked domain of at least about 2,000 bp in length, wherein said P-foot flanked domain comprises...”.

Claims 11, 27 and 31 are also amended to delete the phrase “wherein said single transcriptionally active gene is separated from one of said P-element transposase recognized insertion sequences by a distance of about 1,000 bp or less.” Claims 42-44 are newly added. Each of Claims 42-44 specifies that the transcriptionally active gene is about 1000 bp or less from one of the P-element recognized insertion sequences. Support for this amendment is found at page 6, lines 11 to 25 of the specification, which reads:

In the subject vectors, the pair of P element encoded transposase recognized insertion sequences (i.e. P feet) flank at least one transcriptionally active gene that is in approximation to, i.e., is sufficiently close to or sufficiently proximal to, at least one of the P feet so as to provide for the desired genomic integration. By at least one is meant one or more, usually no more than five, and more usually no more than four, where the number of transcriptionally active genes in the vector is often one, two, or three, where only one of the transcriptionally active genes need be sufficiently proximal to the P foot. By in approximation to, i.e., sufficiently close or proximal to, is meant that the transcriptionally active gene is located at a distance from one of the flanking P-feet that typically is less than about 7000 bp and often less than about 6,000; 5,000; 4,000; 3,000; or 2,000 bp, where in many embodiments the distance separating the transcriptionally active gene from the P foot does not exceed about 1,000 bp. In certain embodiments, the exogenous nucleic acid that is inserted into the genome of a whole animal in the subject methods, described in greater detail *infra*, is one of the transcriptionally active genes of the vectors.

As no new matter is added by way of these amendments, entry thereof by the Examiner is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, second paragraph

Claims 11, 13-15, 18, 27, 30, 31 and 34 were rejected under 35 U.S.C. § 112, second paragraph, on the grounds that “it is unclear if there are two sets of flanking P-feet.” This rejection has been addressed by amendment and may now be withdrawn.

Claim Rejections – 35 U.S.C. § 102

Claims 11, 13-15, 18, 27, 30, 31 and 34 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Fogarty et al. (U.S. Patent No. 6,291,243) (hereinafter “the '243 Patent”). The rejection is respectfully traversed.

An element of independent Claims 11, 27 and 31 is “a pair of P element transposase recognized insertion sequences flanking a single transcriptionally active gene.”

At page 4 of the Office Action mailed September 15, 2008, the Examiner asserts that the '243 Patent anticipates this claim element by referring to col. 5, lines 5-9 of the '243 Patent, which states:

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vectors that include a single transcriptionally active gene. In
vectors of this embodiment of the subject invention, the
promoter that is part of the transcriptionally active gene may
be any of those described above, e.g. SV40, with the proviso
that the promoter is not a CMV promoter. Vectors of this
embodiment that include a single transcriptionally active
gene may be prepared and used as described below, where
the following description is provided in terms of vectors that
include at least two transcriptionally active genes.
Methods of Preparing the Subject Vectors

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The enclosed declaration indicates that to the extent that this particular claim element is disclosed (if at all) in the specification of the '243 Patent, this particular claim element was not conceived of by Joseph Lipsick, but rather by Patrick Fogarty.

As such, the '243 Patent represents the Applicants' own work and does not qualify as work "by another" under 35 U.S.C. §102(e).¹

Accordingly, the '243 Patent is not available as prior art and withdrawal of the rejection under 35 U.S.C. § 102(e) is appropriate and respectfully requested.

To the extent the Examiner's rejection is based on a reference to the pCasper4 vector in Figure 2, it is noted that the '243 patent never teaches introduction of the pCasper4 alone into a host. pCasper4 is used to make the gene transfer vector but is not introduced by itself into a host.

For all the reasons presented above, new Claims 42-44 are also patentable over the art and an indication of allowance thereof is respectfully requested.

¹ As noted by the Examiner on page 3 of the Office Action mailed September 15, 2008, and page 3 of the Office Action mailed September 10, 2007, under M.P.E.P. §715.01(c), §716.10 and §2136.05, when the applicant is the inventor of the subject matter disclosed in a patent or published application cited against his or her application, he or she may overcome the rejection by filing a declaration to establish that the patent or published application describes the applicant's own work. Such a declaration by the applicant is sufficient to remove the patent or published application as a reference under 35 U.S.C §102(a) and (e) (*In re Katz*, 687 F.2d 450, 455, 215 USPQ 14, 18 (CCPA 1982) and *In re Matthews*, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969)).

CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Office finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number TOSK-007CON.

Respectfully submitted,
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